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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,213	07/07/2003	William E. Bay	1946/1G906-US2	8060

7590 03/16/2006

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805 Third Avenue  
New York, NY 10022

EXAMINER
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DESAI, RITA J

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/615,213

Applicant(s)

BAY ET AL.

Examiner

Rita J. Desai

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-5,7-9,11-22 and 29-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 7-9, 11-22, 29-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/28/05</u> | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 1, 3-5, 7-9, 11-22 ,29-66 are pending.

The rejection of the claims 1, 3-5, 7-9, 11-22 and 29 and the new claims 30-66 under 35 USC 103 over WO9630036 still stands.

The reference clearly teaches the delivery agents and their salts. It does not specifically call it a disodium salt but the presence of 2 available H ions would give a disodium salt in an excess of sodium hydroxide or sodium ethoxide.

The new compound as given in claims 59 has also been disclosed. See WO 97/36480 . The use of these salts is the same as given in the prior art. Thus with out any showing that their compounds have unexpected results the claims are prima facie obvious.

The US 5773647 Andrea Leone-Bay et al discloses the delivery agents of the invention and its salts. So does WO9736480 . They do not specify the di sodium salt however they do specify the Na or K salts. Just salts.

However see WO 95/28838 Leone-Bay et al which also discloses the modified amino acids for drug delivery. See page 12 line 30 , which specifically states that if the amino acid is multifunctional i.e. has more than one –OH group then it may also be optionally be acylated to form an ester which is then subsequently hydrolyzed.

So it is obvious from the teachings of '838 , that since the compound of formula as given in claim 1, has two –OH groups it could be converted to a disodium salt as the reference teaches

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using NaOH to hydrolyze the modified ester, and so one of skill in the art would have been motivated to make the disodium salt. See pages 9 and 10 of the reference.

US 4757066 Shiokari et al teaches a number of delivery agents which are dissolved by adding NaOH and raising the pH, then the active ingredient is also dissolved and the solution used for delivery. See example 1-3 in column 35 and 36 of the reference. Thus the Na salt helps in the formation of a solution which is convenient for drug delivery.

Also sodium salts are commonly used in pharmaceuticals since they make the drug more soluble. So the delivery agents and the methods of the instant invention are obvious variants of US '647, WO'480, US '066 and WO'838.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5, 9, 13-22 and 29-58, 64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite R5 being substituted or unsubstituted. Also it states

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alkylarylene or aryl(C1-C12 alkylene). There is no written description and definition of these groups in the specifications.

It does not describe which groups are included and which are not.

Also the active agents are described in functional language and its meets and bounds are not clear.

The expression “ growth hormones, interferons, human recombinant insulin , analogs, vitamins, fragments and so on and so on.....” without i.e. partial or complete structure does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. The functional language recited without any correlation does not meet the written description requirement for the expression “growth hormones, interferons, human recombinant insulin and analogs, vitamins, fragments and so on “ as one of ordinary skill in the art could not recognize or understand the structure from the mere recitation of the function. Claims employing functional language at the point of novelty, such as applicants’, neither provide those elements required to practice the inventions, nor “inform the public” during the life of the patent of the limits of the monopoly asserted. The expression could encompass myriad of compounds and applicants claimed expression represents only an invitation to experiment regarding possible compounds.

### ***Conclusion***

The claims 1, 3-5, 7-9, 11-22 ,29-66 are rejected.

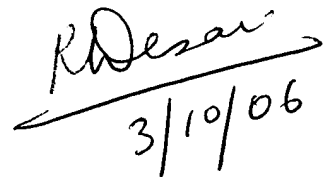
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai  
Primary Examiner  
Art Unit 1625

Handwritten signature of Rita J. Desai and the date 3/10/06.

R.D.  
March 9, 2006